

Memorandum of Telephone Conversation

Date: January 4, 2001

Between: Michelle Butler, Hyman, Phelps & McNamara, P.C., Washington, D.C.,  
(202) 737-7551

and

Gerald M. Rachanow, Regulatory Counsel, Division of OTC Drug Products, FDA

Subject: BC Analgesic Powder (Two Doses)

I called Robert A. Dormer, Esquire, about his December 22, 2000 letter to Dr. Charles Ganley, coded as AMD1 in Docket No. 98N-0337. That letter was in response to the Division of OTC Drug Products' letter of August 28, 2000 concerning an Application for Exemption for BC Analgesic Powder (two doses).

My call was returned by Michelle Butler, Esquire. I informed Ms. Butler that we would like an explanation of a sentence that appears on the second page of Mr. Dormer's letter that states under Option 1 that "The information required by the Regulation would be presented with some modifications to the formatting and type size requirements." I explained that it was not clear to us what these modifications would be and asked that he clarify this statement to identify the modifications so that information would be clear to us while evaluating the petition. I asked that a written explanation be provided (3 copies to the docket and a desk copy to Dr. Ganley). Ms. Butler stated that she would inform Mr. Dormer of our conversation, which concluded amicably.

*Gerald M. Rachanow*  
Gerald M. Rachanow, P.D., J.D.

98N-0337

MT 1

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE:

Jan. 10, 2001

FROM:

Director

Division of OTC Drug Products, HFD-560

SUBJECT:

Material for Docket No. 98N-0337

TO:

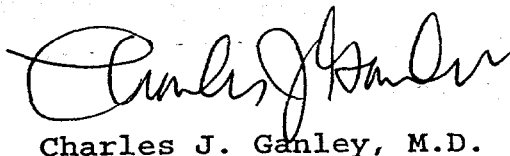
Dockets Management Branch, HFA-305



The attached material should be placed on public display under the above referenced Docket No.



This material should be cross-referenced to Comment No. AMD1

  
Charles J. Ganley, M.D.

Attachment